RÉSEAU DE SANTÉ Horizon HEALTH NETWORK	**STANDARD OPERATING PRACTICE** **Office of Research Services**
Authority and Scope of Horizon's Human Research Protection Program	
SOP No.: 1	**Effective Date: June 1, 2023** Initial version: March 26, 2020

PURPOSE

To communicate the origins of and the organizational authority under which Horizon's Human Research Protection Program (HRPP) is established and empowered. This includes statements of the HRPP's mandate, authority and scope, as well as the principles governing the HRPP to ensure that the rights and welfare of participants are protected.

DIRECTLY AFFECTED

Unless explicitly stated, this policy applies to the persons or groups listed below exclusively.

- Researchers, Research Coordinators, and Research Assistants.
- Research Ethics Board.
- Regional Director Research Services.
- Regional Director Ethics Services.
- Office of Research Services (ORS).
- Vice-President Medical, Academic and Research Affairs.
- Executive Leadership Team for Horizon.
- Horizon Board of Directors.

PROCEDURE

Origins and Institutional Authority

Through its Executive Leadership Team, Horizon Health Network (Horizon) has established a Human Research Protection Program (HRPP). The HRPP is an institution-wide program for protecting Horizon's human research participants involved in research carried out under its auspices regardless of where the research is conducted that came into effect July 1, 2018. The HRPP reports to the Horizon Executive Leadership team through the VP, Medical Affairs, Education and Research; the Research Ethics Board component of the HRPP reports to the Board of Directors for Horizon to ensure it functions independently and is free from any undue influence with respect to its deliberations and decisions.

Mandate

The mandate of the HRPP is to:

- Safeguard and promote the health and welfare of human research participants by ensuring that their rights, safety, and well-being are protected.
- Provide guidance and support to the research community in the conduct of research with human participants.
- Assist the research community in ensuring compliance with relevant regulations.
- Provide timely and high-quality review and oversight of human research projects.

- Promote a culture of research excellence through a systemic approach that places great value on the conduct of scientifically sound and ethically acceptable human participant research.
- Provide standardized methods allowing parallel reviews between Horizon REB and other entities such as other health Institution REB adopting HRPP reviews and processes.

Scope of HRPP:
The HRPP shall review all research involving human participants where the research is:

- At or using a Horizon facility.
- By or under the direction of any employee or agent of Horizon (including students), in connection with their Horizon position or responsibilities.
- Using Horizon's non-public information (e.g., patient medical records).

Approval, Updates and Revisions to the Mandate
The Mandate of the HRPP was approved by the VP Medical Affairs, Education and Research, The Executive leadership Team (ELT) of Horizon, The Research Ethics Board, The Regional Director of Research Services, and the Board of Directors for Horizon. Any substantive revisions or updates to the mandate will be subject to their approval.

The process for approving substantive revisions or updates to the mandate will be as follows:

- The revised mandate will be reviewed by the VP, HRPP Director and the Regional Director of Research Services.
- It will then be forwarded to the REB for review at a convened meeting. Discussions and deliberations will be captured in the minutes of the meeting at which it was reviewed. the VP will then provide the revised mandate to ELT at a convened meeting with subsequent reporting to the Horizon Board of Directors.

For those interested, this Mandate has been translated into French (Appendix A).

Organizational Structure of the HRPP

The HRPP consists of individuals, departments and committees with responsibilities for human research protection: Horizon executive leadership; Horizon Board of Directors; the Offices of Research Services and of Research Ethics; the Regional Director of Research Services; the Regional Director of Ethics Services; the members of the Research Ethics Board; staff with assigned responsibilities for HRPP operations; investigators; research staff; and others.

Individuals who Play a Role in the HRPP

Vice President Medical, Academic and Research Affairs

The Vice-President (VP) Medical, Academic and Research Affairs is the Institutional Authority for the HRPP, and as such:

- Fosters a culture that supports the ethical conduct of research.
- Fosters a culture that supports ongoing quality improvement of the HRPP though education, training for those who play a role in the HRPP and through support of the quality assurance program for the HRPP.

- Is responsible for ensuring that the HRPP has adequate resources to the support size and complexity of the research conducted as well as support necessary to comply with all organizational policies, laws, and regulations that govern human participant research.
- Ensures that the HRPP is adequately insured and has access to legal counsel.
- Ensures that the REB functions independently from Horizon with respect to its deliberations and decisions.
- Ensures the REB is provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties.

As the HRPP's Institutional Authority, the VP has the appropriate training in human research protection and the legal authority to represent the HRPP. Further, the VP has the authority to suspend, terminate, or disapprove research or take other actions, such as sanctions or restrictions of research privilege or uses of research data, as necessary, to ensure the proper conduct of research, the protection of human participants, the autonomy and authority of the REB, compliance with regulation or policy, or to protect the interests of Horizon. However, the VP may not approve research that has been disapproved (or not yet approved) by the REB.

HRPP Director

The VP also has the authority to delegate the performance of certain oversight and operational duties to an HRPP Director if such delegation is not contrary to HRPP policies and procedures. This Director must be qualified through education and training in human research protection.

Reporting indirectly to the VP through the Regional Director of Research Services, the HRPP Director is responsible for the day-to-day operation of the HRPP. This includes:

- Fostering a culture that supports the ethical conduct of all human research and adherence to all regulations, standards, guidelines, and policies listed in the Mandate.
- Overseeing the education and training program for those who play a role in the HRPP.
- Facilitating the regulatory and methodological components of the institutional review process for all research studies submitted to the HRPP.
- Ensuring that there are sufficient resources for auditing and conducts regular auditing activities to evaluate compliance of both individual research studies and of the HRPP overall.
- Ensuring that any corrective or preventative actions, or areas for improvement, identified in an audit are addressed in a timely manner.
- Ensuring that Investigators/Researchers under the HRPP are fulfilling their responsibilities.
- Conducting an annual, formal, and documented review of the HRPP and making adjustments, as required.

If operations require, the Director will delegate some or all of their responsibilities to another HRPP member. However, the Director maintains responsibility for the conduct of their delegates and ensures that all HRPP members have the appropriate education and training before undertaking their delegated responsibilities.

Regional Director, Research Services

Through the Regional Director of Research Services who reports directly to the VP Medical, Academic and Research Affairs, the Office of Research Services (ORS) provides support to the HRPP by working collaboratively with the HRPP Director to assist in implementation of the program. The Regional Director also ensures that there are sufficient resources for auditing activities to evaluate compliance of both individual research studies and of the HRPP overall and that that any corrective or preventative actions, or areas for improvement, identified in an audit are addressed in a timely manner.

Regional Director, Ethics Services

Reporting directly to the VP Medical, Academic and Research Affairs, the Regional Director oversees the operations of the Research Ethics Board. The Director is also a member of the REB and has extensive knowledge and experience in the area of ethics of human participant research. The Regional Director will work collaboratively with the Regional Director of Research Services and the HRPP Director to ensure that:

- A culture is fostered that supports the ethical conduct of all human research.
- The REB members have access to applicable education and training.
- Any corrective or preventative actions, or areas for improvement, identified in an audit are addressed in a timely manner and,
- That Investigators/Researchers under the HRPP are fulfilling their responsibilities.

Research Ethics Board (and Administrative Personnel)

Horizon's Research Ethics Board (REB) reviews and advises on all ethical aspects of proposed research. The REB functions independently of, but in coordination with, other committees and officials with responsibilities related to human participant research. However, the REB makes its independent determination whether to approve or disapprove research, based upon whether or not human participants are adequately protected and, whether the proposed research is scientifically valid and has social and clinical value.

Research that has been reviewed and approved by the REB may be subject to review and disapproval by officials of the organization. However, those officials may not approve human research that has not been approved or has been disapproved by the REB.

The REB membership is intended to ensure inclusivity, geographic representation from areas under Horizon jurisdiction and that the REB has the expertise and independence essential for conducting competent research ethics reviews.
The Horizon REB is composed of members with expertise in the following areas (please refer to REB Composition policy, HHN-RS-002):

- One Chairperson.
- At least one methodological expert.
- At least one content expert for each of the areas of research most commonly reviewed by the REB.
- At least one expert in ethics.
- Two members whose primary experience and expertise are in a scientific discipline who have broad experience in the methods and areas of research to be approved and one of whom is from a medical discipline or, if the clinical trial is in respect of a drug to be used for dental purposes only, is from a medical or dental discipline.
- At least one member whose primary expertise is in a non-scientific discipline.

- At least one member knowledgeable in the Canadian law relevant to the research to be approved; NOTE: That member should not be the institution's legal counsel or a risk manager.
- At least one community member with no affiliation with Horizon but recruited from the community served by Horizon and has relevant experience or training.
- And substitute members.

Board members will have the qualifications, expertise and training necessary to review the ethical issues raised by research proposals that fall within the jurisdiction of research conducted in Horizon. There is a strict selection process for members of the REB and nominations must be approved by the Regional Director of Ethics Services, the REB Chair and the VP Medical, Academic and Research Affairs.

REB Administrative Personnel

REB Personnel are qualified through education and training to provide expertise and administrative support to the REB and serve as a link between the REB and the research community.

Horizon REB's Administrative personnel is composed by 2 dedicated budgeted administrative assistants.

Horizon Health authority will determine responsibility for the recruitment, hiring, and termination of REB Office Personnel in accordance with organizational policies.

REB office personnel responsibilities may include:

- The pre-review of submissions to the REB,
- Preparation of all correspondence to REB applicants and prepare for REB meetings.
- The management of administrative issues involving the provision of advice and information to the REB and researchers

Training of REB Administrative Personnel

The REB Chair or designee will provide new REB Administrative Personnel with an overall orientation to the REB including a general overview of the policies and procedures pertinent to their role in support of the REB.

REB Administrative Personnel will:

- Receive training on the new HRPP SOPs.
- Be expected to be knowledgeable and compliant with the relevant SOPs.
- Be encouraged to complete additional and ongoing relevant education and training in research ethics and in the conduct of research.
- Be encouraged to engage in self-directed learning to enhance their ability to fulfill their responsibilities.
- Be required to undergo annual performance review by the Chair or designee.
- Be required to disclose any conflicts that arise and any REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves when such research is reviewed.

Principal Investigators/ Researchers and research personnel

Principal Investigators (PIs) are ultimately responsible for the conduct of research. Investigators may delegate tasks to appropriately trained and qualified members of their research team.

However, PIs must maintain oversight and retain ultimate responsibility for the proper conduct of the research. The PI is expected to abide by the highest ethical standards when developing a research plan. The PI is expected to conduct research in accordance with the REB approved research plan and to personally conduct or oversee all aspects of the research.
In addition to complying with all applicable regulatory policies and standards, PIs must comply with organizational and administrative requirements for conducting research. The PI is responsible for ensuring that all co-investigators and research staff complete all required training as well as training for their delegated responsibilities in any given specific research study. When investigational drugs or devices are used, the investigator is responsible for ensuring an appropriate plan for storage, security, dispensing, accounting, and disposal.

The REB reviews investigator qualifications when reviewing research and may determine that an investigator may not serve as PI or may require the addition of other investigators, for example, to supplement the expertise available on the research team or to conduct or oversee certain research activities.

The Principal Investigator for research under Horizon's jurisdiction generally must be employed by or have privileges at a Horizon facility. Students and residents must work under the mentorship of appropriate Horizon personnel and may serve as PI but mentorship by an appropriate leader is encouraged.

Components of Institutional Review

The components of institutional review ensure that no research study can commence without:

- Meeting institutional requirements for compliance and methodology (which includes evidence of authorization from the appropriate regulatory authority if applicable, and evidence of support from the organizations impacted departments)
- Final REB approval.

Regulatory Review

Research Services staff with significant clinical research experience and certifications in clinical research coordination, and/or privacy information management from national accrediting bodies, are assigned by the HRPP Director to review projects for regulatory compliance with federal regulations, provincial law, and organizational policies.

The relevant guidelines, regulations, policies, and standards governing the HRPP:

Canadian Legislation

Health Canada Food and Drugs Act https://laws-lois.justice.gc.ca/eng/acts/F-27/page-1.html

Personal Information Protection and Electronic Documents Act (PIPEDA) https://laws-lois.justice.gc.ca/ENG/ACTS/P-8.6/page-1.html

Canadian Regulations

Health Canada Food and Drugs Regulations, Part C, Division 5 https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-133.html#h-577812

Health Canada Natural Health Products Regulations, Part 4 https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/clinical-trials.html

Health Canada Medical Device Regulations, Part 3 https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-9.html#h-1021976

Policies and Guidelines

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2022) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) (ethics.gc.ca)

International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice Guideline https://www.ich.org/page/efficacy-guidelines

Other Regulations US Code of Federal Regulations Title 21 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

US Code of Federal Regulations Title 45 https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45tab_02.tp

Regulation Title 56 https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56

Note: Federalwide Assurance (FWA) and IRB Registration: The federal regulations require that federally funded human subject research only be conducted at facilities covered by a Federalwide Assurance (FWA) approved by the DHHS Office for Human Research Protections (OHRP). An FWA is an organization's assurance to the federal government that human participant research conducted at that site complies with federal regulations pertaining to the protection of human participants. Horizon's FWA# 00016955

Standards

CAN/HRSO – 100.01 – 2020 Development of a Human research Protection Program (HRPP) https://www.hrso-onrh.org/hrso/wp-content/uploads/CAN.HRSO-100.01-2020-English.pdf

CAN/HRSO – 200.01 – 2021 Ethical review and oversight of human research

https://www.hrso-onrh.org/hrso/wp-content/uploads/CAN.HRSO-200.01-2021-English.pdf

Provincial Legislation

New Brunswick's Personal Health Information Privacy and Access Act (PHIPAA) (2009) https://www.canlii.org/en/nb/laws/stat/snb-2009-c-p-7.05/latest/snb-2009-c-p-7.05.html

Methodology Review

ORS staff with relevant expertise evidenced through experience and/ or training in research methodology and design are assigned by the HRPP Director to review and evaluate research projects for scientific validity of the proposed research. This review considers whether:

- There is a testable and unambiguous research question (for quantitative methods).
- The research purpose is clear (for qualitative methods).
- The study is properly designed to produce data suitable for analysis.
- The results/conclusions directly address the questions being asked.

Research studies that meet regulatory and methodologic requirements are forwarded to Horizon's Research Ethics Board (REB) for review and approval. If there is an unresolved disagreement between Investigators/researchers or Sponsors, and those reviewing the project for regulatory compliance or methodology, the Project will be forwarded to the Research Ethics Board with comments appended for the REB's consideration. The REB will determine whether the project is eligible for REB review based on the comments from the regulatory and or methods review. The VP will be notified of any such disagreements.

Research Ethics Board Review

The membership of Horizon's Research Ethics Board will conduct a competent and independent research ethics review to determine that the proposed research is scientifically valid and has value to affected communities.

The REB upholds and adheres to the principles of *Tri Council Policy Statement*: *Ethical Conduct for Research Involving Humans* by the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada (2022):

- *Respect for Persons*, which involves obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.
- *Concern for Welfare*, which involves ensuring that possible benefits are maximized, and possible risks are minimized to all human participants.
- *Justice*, which refers to the obligation to treat people fairly and equitably.

The REB has the authority to:

- Approve, require modifications to secure approval, or disapprove human participant research.
- Require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the REB.
- The REB may require that information, in addition to that specifically mentioned in the regulations, be given to the participants when, in the REBs judgment, the information would meaningfully add to the protection of the rights and welfare of participants.
- Conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year.
- Suspend or terminate approval of research not being conducted in accordance with the REB's requirements or that has been associated with unexpected serious harm to participants.
- Observe, or have a third party observe, the consent process.
- Observe, or have a third party observe, the conduct of the research.

Required documents relating to a research project submitted for HRPP review and REB approval are entered into a web-base research portal. Post submission of the project into the portal, members of the Office of Research Services coordinate reviews for contracts (if applicable), methodology and regulatory compliance and impacted departmental support prior to releasing the application to REB for their review. (Please refer to SOP 24 Initial Review Requirements and Ongoing Communication with Horizon's REB for details on documents required for submission).

As per recommendations from the International Committee of Medical Journal Editors (ICMJE), all eligible studies are required to be registered on a publicly accessible website.

Multi-Centre and Multi-jurisdictional Research Studies

Multi-centre and multi- jurisdictional research studies are subject to Horizon's Institutional Review process. The Horizon REB conducts its own independent research ethics review of multi centre research projects and the level of ethics review for research that involves multiple REBs and/or institutions and/or jurisdictions is proportionate to the risk involved in the research.

In order to facilitate collaborative research projects involving researchers, data or participants from more than one institution, and in order to avoid a duplication of efforts with respect to research ethics reviews, the health authority through its authorized signatories may enter into Ethics Review Agreements.
An Ethics Review Agreement may be limited to a specific type of Research.
Prior to entering into an Ethics Review Agreement with another institution, the Horizon REB shall:

- take into account the manner in which the other institution's research ethics board conducts research ethics reviews; and
- consult with the Chairs of the REBs.

HRPP being a collaborative effort between all who develop, conduct, review, approve and facilitate Human Research, and a base for standardized SOP and methods for review, the transition in a multi centre, multi jurisdictional research studies will be facilitated when this may occur.

Contact Horizon's HRPP

As of January 1, 2020, the HRPP Director is *Jacquelyn Legere, Office of Research Services*. If there are questions or concerns about the HRPP, or to schedule a meeting, the HRPP Director can be contacted directly by email: ROMEO@HorizonNB.ca.

RELATED DOCUMENTS

HRPP Organizational Chart
HHN-RS-002 Composition of the Research Ethics Board.
SOP 3 Determining What Constitutes Human Research for Horizon's HRPP Review.
SOP 24 Initial Review Requirements and Ongoing Communication with Horizon's REB.

REFERENCE(S)

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) (ethics.gc.ca), TCPS 2 (2022).

Health Canada, *Guidance Document (GUI-0100): Part C, Division 5 of the Food and Drug Regulations: Drugs for Clinical Trials Involving Human Participants*, August 2019.

International Committee of Medical Journal Editors, *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*, December 2018.

International Conference on Harmonization, Guidance E6 R2: *Good Clinical Practice (GCP) Guideline*, November 2016.

N2 REB SOP Training and Education: *SOP 103 Training and Education.pdf | Powered by Box*, May 2023.

United States Department of Health and Human Services: Code of Federal Regulations. *Title 45 Public Welfare Part 46, Protection of Human Participants*, current as of July 2018.

Unites States Food and Drug Administration: Code of Federal Regulations. *Title 21, Food and Drugs Part 56.107, Institutional Review Boards*, current as of November 2019.

Original Approval		
Date	**Original Author(s)**	**Approved by**
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January 2020	Incorporate reviewer recommendations	HRA Canada
April 2020	Updated effective date to reflect date of accreditation	HRA Canada
August 2021	Updated to reflect new NSC	HRA Canada
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